

REMARKS

The Office Action of December 15, 2004, has been received and reviewed. Claims 1-22 are pending in the application of which claims 6-22 stand withdrawn from consideration as being directed to a non-elected invention. Claims 1-5 stand rejected. Reconsideration is requested.

Rejections under 35 U.S.C. § 102

Claims 1-5 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Lunardi-Iskandar et al. Applicants respectfully traverse the rejections as set forth herein.

Lunardi-Iskandar et al. does not expressly or inherently disclose each and every element of any of claims 1-5 as required for anticipation. Claim 1 is directed towards a method for obtaining information about the capacity or tendency of an oligopeptide of at most 30 amino acids long or a peptide derivative thereof, to regulate expression of a gene comprising the steps of a) contacting the oligopeptide, or peptide derivative thereof, with at least one cell; and b) determining the presence of a NF-kappaB/Rel protein in or derived from the at least one cell. Thus, the oligopeptide and the peptide derivative thereof are not more than 30 amino acids long.

Lunardi-Iskandar et al. does not disclose contacting an oligopeptide of “**at most**” **30 amino acids long** or a peptide derivative thereof with at least one cell to regulate expression of a gene as recited in claim 1. Lunardi-Iskandar et al. used oligopeptides of **greater than** 30 amino acids long for their experiments. (See, US Patent 5,677,275: column 10, lines 49-52). For instance, Lunardi-Iskandar et al. discloses four different forms of human chorionic gonadotropin (hCG), all of which are **greater** than 30 amino acids long. The peptides used include:

1. Intact native hCG, which is 237 amino acids long
2. Native β -hCG, which is 145 amino acids long
3. A fragment of β -hCG, β -hCG₍₁₀₉₋₁₄₅₎, which is 36 amino acids long; and
4. Native α -hCG, which is 92 amino acids long.

(See, *Id.* at column 10, lines 50-52).

The Office Action asserted that “hCG reads on peptide derivative of a biologically active fragment of hCG or beta-subunit of hCG which is not more than 30 amino acids long such as the 109-119 aa beta-hCG oligopeptide (e.g., claim 7 of Lunardi-Iskandar et al).” (Office Action, pages 3-4). Claim 7 of Lunardi-Iskandar et al. depends from claim 2 and is directed towards,

inter alia, a method for treating Kaposi's sarcoma comprising administering a pharmaceutical agent to a patient, wherein the agent is β -hCG (109-119). (See, U.S. Patent 5,677,275 at claim 7). However, Lunardi-Iskandar et al. does not disclose placing the β -hCG (109-119) in contact with at least one cell and determining the presence of a NF-kappaB/Rel protein in or derived from the at least one cell contacted with the β -hCG (109-119) as recited in claim 1.

Thus, Lunardi-Iskandar et al. does not disclose a method for obtaining information about the capacity or tendency of an oligopeptide of at most 30 amino acids long to regulate expression of a gene as recited in claim 1.

Lunardi-Iskandar et al. also cannot anticipate claim 1 since it does not disclose the method of determining the presence of a NF-kappaB/Rel protein in or derived from at least one cell contacted with the oligopeptide of at most 30 amino acids as recited in claim 1. Accordingly, since Lunardi-Iskandar et al. does not disclose each and every element of claim 1, it cannot be anticipated.

Claims 2-5 depend from claim 1 and, thus, include the elements of claim 1. Since Lunardi-Iskandar et al. does not anticipate claim 1, claims 2-5 are not anticipated, at the very least, as depending from novel independent claim 1.

With further regard to claim 5, it cannot be anticipated since Lunardi-Iskandar et al. does not disclose determining the presence of the NF-kappaB/Rel protein in or derived from a cell which has not been contacted with the oligopeptide, or peptide derivative thereof, and determining the **ratio** of the NF-kappaB/Rel protein found in step b) to gene product found in step c).

The Office Action states "[t]he reference teaches that the polypeptide gene product of c-rel was detected in the cells from the mice treated with hCG and not in the cells of mice that had not been treated with hCG (column 13, lines 10-17), which determines the ratio." (Office Action, page 4). However, Lunardi-Iskandar et al. does not disclose detecting any ratio since the word "ratio" does not appear in the cited passage. Thus, claim 5 cannot be anticipated.

Reconsideration and withdrawal of the anticipation rejection of claims 1-5 are requested.

CONCLUSION

In view of the foregoing remarks, claims 1-5 should be in condition for allowance and an early notice thereof is requested. Should questions remain after consideration of the foregoing, the Office is invited to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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